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UNCLAS SECTION 01 OF 02 ANKARA 006279

SIPDIS

DEPT FOR E, EB/TPP/MTA/IPC, EUR/ERA, EUR/SE
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SENSITIVE

E.O. 12958: N/A
TAGS: ETRD KIPR TU
SUBJECT: Update and Next Steps on Pharmaceuticals Issues in Turkey

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Ref: (A) Ankara 5695 (B) 2003 State 322108
(C) Ankara 5385

Summary

¶1. (SBU) The research-based pharmaceuticals industry continues to grapple with a difficult set of challenges in the areas of intellectual property protection (lack of data exclusivity and potential patent infringement) and reimbursement reform (including non-transparent development of restrictive lists of eligible drugs). In response to the EU's threat of WTO dispute settlement or even trade sanctions if Turkey continues to delay data exclusivity, it appears that the GOT is close to a decision to implement protection soon. Washington agencies and Mission elements have actively advocated for the pharmaceuticals companies in the past and will continue to do so. End Summary.

Data Exclusivity

¶2. (SBU) As reported ref A, the EC's Trade Barrier Report (TBR) found that Turkey has not complied with the customs union and TRIPS Agreement requirements on data exclusivity. The EU threatened formal WTO consultations or trade sanctions if Turkey did not agree to implement these by the end of October 2004. Industry sources tell us that this deadline has been extended by several weeks. The Foreign Trade Undersecretary in October hosted a meeting with representatives of both the research-based and generic industries to discuss data exclusivity. Pfizer representatives are cautiously optimistic that the GOT will ultimately agree to move forward implementation of data exclusivity (currently planned for end-2007), perhaps even to retroactive implementation. A Dutch diplomat based in Ankara recently told us that there is interest in several EU member embassies in a joint demarche with the USG on this issue if the GOT does not come up with a satisfactory policy, as Washington had suggested last year (ref B), but we have not heard an authoritative view from the European Union delegation on this matter.

Zyprexa

¶3. (U) Eli Lilly is concerned that generic manufacturers have applied to the Health Ministry for registration of copies of Zyprexa, which has a valid Turkish patent which is not due to expire until 2016. We have raised this issue with the GOT on several occasions (see below).

Reimbursement System Reform and Drug Savings

¶4. (U) As part of its planned social security reform, one of the key structural reforms supported by the IMF and World Bank, the GOT is contemplating reforms in its pharmaceuticals reimbursement systems which will reduce health expenditures, but have a dramatic impact on the industry. A "positive list" of drugs eligible for reimbursement, not yet approved by the GOT, could severely limit Turkish patient access to innovative products by restricting the types of physicians and facilities authorized to prescribe certain drugs. Research-based industry claims that it has not had sufficient opportunity to provide input into the development of this restrictive list. It also objects to GOT pressure to provide significant discounts on drug prices.

Recent Advocacy

¶5. (SBU) Washington agencies and the Mission have advocated aggressively and at high levels on behalf of research-based industry, particularly over the data exclusivity issue. Lack of data exclusivity was the primary reason for elevating Turkey to the Priority Watch List in the 2004 Special 301 Review. Recent advocacy includes:

- Commerce U/S Aldonas' October 29 letter to Foreign Trade Undersecretary Tuncer Kayalar;

- The Ambassador raised the data exclusivity problem in an October 25 speech to the Izmir Chamber of Commerce on investment issues, as well as in his opening remarks at a September 9 conference for Turkish judges and prosecutors on intellectual property enforcement;

- The Ambassador told State Minister Tuzmen that Turkey is not complying with its WTO TRIPS obligations on data exclusivity in a September 17 meeting (ref C);

- Commerce DAS Stewart's September 9 meeting with the Health Ministry's General Director for Pharmaceuticals, the Deputy U/S Foreign Trade, and other GOT officials;

- The Ambassador's August 19 letter to Health Minister Akdag urging that the Ministry not approve patent-infringing copies of Eli Lilly's Zyprexa drug.

Next Steps

¶6. (SBU) Post sees results from our and EU pressure on GOT. The dialog between Pharma companies and senior GOT officials seems to have improved. We will continue to press the Turks to implement data exclusivity immediately, involve industry stakeholders fully in reimbursement reform, and refrain from approving generic copies of drugs which should enjoy patent protection. As noted above, Turkey's data exclusivity policy may improve in the near future in response to the EC's TBR report. Mission has requested meetings with the Health Ministry U/S as well as the President of the Turkish Patent Institute on these issues. We will also ensure that visiting economic officials are briefed and have the opportunity to raise pharmaceuticals issues with decisionmakers in the GOT. We should also use the next Trade and Investment Framework Agreement (TIFA) meeting, likely to be held in early 2005 in Ankara, to further our objectives in this area.
Edelman